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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,521	03/19/2001	Caroline Kreutzer	P 278416 980183 BT-CIP	6186
909	7590	05/14/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			RAMIREZ, DELIA M	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1652

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/810,521

Applicant(s)

KREUTZER ET AL.

Examiner

Delia M. Ramirez

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 1,16,22,23,27,30 and 31.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 28,32.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

***ADVISORY ACTION***

1. Claims 1, 16, 22-23, 27-28, and 30-32 are pending.
2. The period for reply continues to run from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 must be timely filed to avoid abandonment of this application.
3. The request for entering amendments to claims 1, 27, 30-31, cancellation of claim 3, and arguments filed on 4/15/2004 under 37 CFR 1.116 in reply to the Final Action mailed on 1/21/2004 are acknowledged. The proposed amendments to the claims will be entered since they are deemed sufficient to overcome the claim objections, 112 second paragraph rejections and some of the grounds of rejection under 112, first paragraph previously applied. However, entry of these amendments is not deemed sufficient to place the application in condition for allowance for the following reasons.
4. Claims 28 and 32 would remain rejected under 35 USC 112, first paragraph for lack of adequate description and enablement. Applicants argue that there is sufficient written descriptive support for one of skill in the art to understand overexpression of the lysC gene refers to copy number, strong promoters or means to stabilize mRNA. Furthermore, Applicants submit that the specification is enabling for overexpression by increasing the copy number, enhance the promoter or increase the regulatory region of the ribosome binding site of the gene of interest. Applicant's arguments have been fully considered but are not deemed persuasive in regard to claims 28 and 32 for the following reasons. Claims 28 and 32 are still directed to the bacteria of claims 27 and 31, respectively, wherein said bacteria expresses a genus of mutant *C. glutamicum* lysC genes modified in any way such that the aspartate kinase encoded by said mutant lysC gene is resistant to inhibition by lysine and/or threonine. As indicated in the Final Action,

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while the specification discloses that EP-B-0-387-527 teaches a single mutant *C. glutamicum* lysC gene encoding an aspartate kinase which is resistant to inhibition by lysine and/or threonine, the specification fails to disclose the structure of said mutant lysC gene. Furthermore, the specification does not provide any teaching as to which are the structural elements in the *C. glutamicum* lysC gene which can be modified such that the encoded aspartate kinase would be resistant to inhibition by lysine and/or threonine, or what these modifications are. Thus, one cannot reasonably conclude that there is adequate written description of the bacteria of claims 28 and 32. Since structure determines function, one of skill in the art would require some knowledge or guidance as to the correlation between the structure of the wild-type *C. glutamicum* aspartate kinase encoded by the lysC gene and inhibition by lysine and/or threonine. In view of the fact that no information has been provided regarding the structure of the mutant lysC gene which encodes an aspartate kinase resistant to inhibition by lysine and/or threonine, and there is no teaching in the specification or the art as to all the structural elements in the wild-type *C. glutamicum* lysC gene which can be modified to encode an aspartate kinase having resistance to inhibition by lysine and/or threonine, one of skill in the art would have to go through the burden of undue experimentation to enable the full scope of the claims.

5. The rejections previously applied to claims 28 and 32 are, therefore, maintained for the reasons of record and those indicated above.

6. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: 1, 16, 22-23, 27, and 30-31

Claims(s) objected to: NONE

Claim(s) rejected: 28 and 32

Claim(s) withdrawn from consideration: NONE

7. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the

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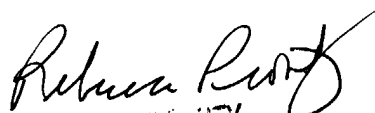
notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
May 11, 2004

  
REBECCA P. P. P.  
PATENT EXAMINER I  
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